The Georgia State Board of Pharmacy met on November 14, 2006, at the Office of the Professional Licensing Boards Division, 237 Coliseum Drive, Macon, GA 31217.

Members Present:

- Bill Prather, President
- Judy Gardner, Vice-President
- Pat McPherson
- Charles Palmer
- Mickey Tatum
- Robbie Dial
- Fred Barber
- Eddie Madden-attended meeting until 12:00 noon.

Visitors:

Mary Ellen Pike,Hobbs & Associates
Othniel Tyrus Smith, RPH

Staff Present:

- Janet Wray, Attorney General's Office
- Rick Allen, Deputy Director, Georgia Drugs and Narcotics Agency
- Lisa Durden, Executive Director
- Sandy L. Bond, Executive Director
- Dianne W. Patterson, Administrative Assistant

Absent:

- Bill Atkins, Director, Georgia Drugs and Narcotics

Mr. Prather established that a quorum was present, and called the meeting to order at 10:00 a.m.

Mr. Tatum moved, Ms. Gardner seconded, and the Board voted to enter into **EXECUTIVE SESSION** in accordance with O.C.G.A §§43-1-19(h) (2) and 43-1-2(k) to review applications, deliberate on disciplinary matters, and to receive information on investigative reports. Voting in favor of the motion were those present who included Board Members Mr. Madden, Mr. McPherson, Mr. Dial, Mr. Barber and Mr. Palmer.

At the conclusion of the EXECUTIVE SESSION, the Board declared an **Open Session** to vote on the matters discussed in Executive Session and to conduct other Board business.

APPOINTMENT (S)

- The Board met with R.O.H., Spouse, Mr. Toliver, Attorney and Advocate to discuss possible reinstatement of a Georgia Pharmacist license.

R.O.H.: Mr. Tatum made a motion to **approve R.O.H.**'s request for reinstatement of his Georgia Pharmacist Intern license. The case will be forwarded to the Attorney's General Office for drafting of a Private Consent Order. Mr. Palmer seconded the motion and it carried unanimously.

Janet Wray, Board Attorney General's Office:

Mrs. Wray updated the Board on all open cases in the Attorney General's Office and presented one Private Consent Order, one Consent Order for Licensure and four additional cases:

- **D.B.:** Mr. Palmer made a motion to accept the signed Private Consent Order. The motion was seconded by Mr. Tatum and it carried unanimously.

- **Carrie Elizabeth Creel,RPH021859:** Mr. Palmer made a motion to accept the signed Consent Order. The motion was seconded by Mr. Tatum and it carried unanimously.

- **S.G.P.:** Mr. Palmer made a motion to refer case to Drugs and Narcotics Agency for investigation. The motion was seconded by Mr. Tatum and it carried unanimously.

On behalf of Bill Atkins, Director, Georgia Drugs and Narcotics Agency:
Report was presented by Rick Allen, Deputy Director, Drugs and Narcotics Agency:

- **Kaiser: Mail Orders meet the law requirements.**
- **Rule: Penalties, Chapter 480-15 will be tabled until next Board meeting, December 6, 2006**

Judy Gardner, Cognizant Board Member reported on the following cases:

Judson L. Mullican, RPH11273,GDNA Complaint #A-27822: The cognizant member recommended referring the case to the Attorney General's Office for a Public Consent Order to include a fine of $2,500 and five year probation. Mr. Tatum made a motion to accept the cognizant's recommendation. Mr. Barber seconded the motion and it carried unanimously.

GDNA Complaint #A-27869: The cognizant member recommended dismissing the case. Mr. Palmer made a motion to accept the cognizant's recommendation. Mr. Barber seconded the motion and it carried unanimously.

Mark Dewayne Sharer,RPH12932,GDNA Case #06-35: The Cognizant member recommended accepting the signed Public Interim Consent Order by the Pharmacist. Mr. Tatum made a motion to accept the cognizant's recommendation. Mr. McPherson seconded the motion and it carried unanimously.

GDNA Case #06-37: The Cognizant member recommended accepting the signed Private Interim Consent Order by the Pharmacist. Mr. Tatum made a motion to accept the order. Mr. Barber seconded the motion and it carried unanimously.

GDNA Case #06-36: The Cognizant member recommended referring the case to Drugs and Narcotics Agency for an Investigative Interview. Mr. Tatum made a motion to accept the cognizant's recommendation. Mr. Palmer seconded the motion and it carried unanimously.

Lisa Durden Executive Director's Report:

- Complaints: Streamlining process of old and new complaints.
- Board of Pharmacy Newsletter: Will be requesting Board members to write articles.
- Board of Pharmacy Renewals: On-line renewals have been generated. A 3% audit was conducted for continuing education requirements.
- Sandy Bond was also present and discussed the contract for the newsletter.

President Prather established that a quorum was present, and called the Board meeting to order at 1:00 p.m. for the Public Hearing.

Visitors:
Mary Ellen Pike, Hobbs & Associates
Othniel Tyrus Smith, RPH

Public Hearing, Rule Chapter 480-11 Pharmaceutical Compounding: Mr. Dial made a motion to vote to Adopt Rule Chapter 480-11. Mr. McPherson seconded the motion and it carried unanimously.

PHARMACEUTICAL COMPOUNDING

480-11-.01 Definitions.
480-11-.02 Compounded Drug Preparations ~~Products~~.
480-11-.03 Organization and Personnel.
480-11-.04 Facilities and Equipment.
480-11-.05 Drug Compounding Controls.
480-11-.06 Labeling and Control of Excess Preparations ~~Products~~.
480-11-.07 Control of Components and Drug Preparation ~~Product~~ Containers and Closures.

480-11-.08 Records and Reports.
480-11-.09 Quality Assurance Program for Compounding and Preparation of Sterile Pharmaceuticals.
480-11-.10 Exceptions.

480-11-.01 Definitions.

(1) "Administer" or "administration" means the provision of a unit dose and/or doses of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.

(2) "Barrier Isolator" means an isolator specifically designed for compounding pharmaceutical ingredients or preparations in an aseptic environment.

~~(2)~~ (3) "Biological safety cabinet" means a ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection ~~containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to the National Sanitation Foundation (NSF) Standard 49~~.

~~(3)~~ (4) "Board of Pharmacy" or "Board" means the Georgia State Board of Pharmacy.

~~(4)~~ (5) "Class 100 Environment" or "ISO Class 5" means an atmospheric environment which contains fewer than 100 particles 0.5 microns or larger in diameter per cubic ~~foot~~ meter of air.

~~(5)~~ (6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the
preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

~~(6)~~ (7) "Component" means any ingredient intended for use in the compounding of a drug preparation ~~product~~, including those that may not appear in such preparation ~~product~~.

~~(7)~~ (8) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

~~(8)~~ (9) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

~~(9)~~ (10) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician" or "Rx Only."

~~(10)~~ (11) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a patient.

~~(11)~~ (12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

~~(12)~~ (13) "Drug" means:

(a) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and

(d) Articles intended for use as a component of any articles specified in subparagraph (a), (b), or (c) of this paragraph but does not include devices.

~~(13)~~ (14) Drug regimen review includes but is not limited to the following activities:

(a) Evaluation of any prescription drug order and patient record for:

1. Known allergies;

2. Rational therapy-contraindications;

3. Reasonable dose and route of administration; and

4. Reasonable directions for use.

(b) Evaluation of any prescription drug order and patient record for duplication of therapy;

(c) Evaluation of any prescription drug order and patient record for the following interactions:

1. Drug-drug;

2. Drug-food;

3. Drug-disease; and

4. Adverse drug reactions.

(d) Evaluation of any prescription drug order and patient record for proper utilization, including over utilization or under utilization, and optimum therapeutic outcomes.

~~(14)~~ (15) "Enteral" means within or by way of the intestine.

~~(15)~~ (16) "GDNA" means the Georgia Drugs and Narcotics Agency.

~~(16)~~ (17) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or rule.

~~(17)~~ (18) "Nonprescription drug" means a drug which may be sold without a prescription drug order and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and/or the federal government.

~~(18)~~ (19) "Parenteral" means a injectable sterile preparation of drugs for administration by any other means than through the gastrointestinal tract.
~~injection through one or more layers of the skin.~~

~~(19)~~ (20) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the law and the rules of the Board, to the patient, patient's caregiver, or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices.

~~(20)~~ (21) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services and pharmacy care.

~~(21)~~ (22) "Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.

~~(22)~~ (23) "Pharmacy" means any place licensed in accordance with the laws and rules of this state wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the Board at the address for which the license was issued.

~~(23)~~ (24) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

~~(24)~~ (25) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the law and the rules of the Board, prior to dispensing the drug as part of a drug regimen review.

~~(25)~~ (26) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, or any other contaminant including, but not limited to, parenterals, injectables, and ophthalmics.

(27) "Sterile Preparations" are those as defined by USP 797.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.02 Compounded Drug Preparations ~~Products~~.

(1) Compounded drug preparations ~~products~~ Pharmacist.

(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations ~~products~~ that are commercially or not commercially available in the marketplace.

(b) Pharmacists shall receive, store, or use drugs that have been made in a FDA-approved facility. Pharmacists shall also receive, store, or use drugs in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

(c) Pharmacists may compound drugs prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations ~~products~~ compounded at the pharmacy. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing which requires a manufacturer's license.

(d) The distribution of inordinate amounts of compounded preparations ~~products~~ without a prescriber/patient/pharmacist relationship is considered manufacturing.

(e) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order, pharmacists may compound, in reasonable quantities, drug products that are commercially or not commercially available in the marketplace.

(f) Pharmacists shall not offer compounded drugs to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a prescriber to administer to an individual patient.

(g) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable state laws and rules regulating the practice of pharmacy.

(2) If low, medium, and/or high risk sterile preparations are being compounded, they must be in accordance with USP 797 and/or Georgia regulations. ~~Sterile pharmaceuticals. If sterile (aseptic) products are being compounded, conditions set forth in the Board rules for sterile pharmaceuticals must be followed.~~

(3) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

(4) Special precaution preparations ~~products~~. If drug preparations ~~products~~ with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(5) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations ~~products~~ should not be compounded in this cabinet.

(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations ~~products~~.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.

(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.
Authority O.C.G.A. §§ 26-4-4, 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.03 Organization and Personnel.

(1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug preparations ~~products~~ containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(2) Pharmacists who engage in drug compounding, and any other pharmacy personnel, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding procedures and shall maintain that proficiency through current awareness and training and

documentation of that training. Every pharmacist who engages in drug compounding and any other pharmacy staff member who assists in compounding, must be aware of and familiar with all details of these good compounding practices. Records of documentation of training for all personnel must be maintained for a minimum of five (5) years.

(3) All pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations ~~products~~ from contamination.

(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person known at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug preparation ~~product~~ being compounded shall be excluded from direct contact with components, drug preparation ~~product~~ containers, closures, in-process materials, and drug preparations ~~products~~ until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the preparations ~~products~~ being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug preparations ~~products~~.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.04 Facilities and Equipment.

(1) Facilities.

(a) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile preparations ~~products~~ shall be separate and distinct from the area used for the compounding of non-sterile drug preparations ~~products~~. The area(s) used for compounding of drugs shall be maintained in a good state of repair.

(b) Bulk drugs and other chemicals or materials used in the compounding of prescription drug orders must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation shall be provided in all drug-compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute to contamination of any compounded drug preparation ~~product~~. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air dryers or single-use towels.

(d) Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

(2) Equipment.

(a) Equipment used in the compounding of drug preparation ~~product~~ shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug preparations ~~products~~ shall be of suitable composition so that surfaces that contact components, in-process materials, or drug preparations ~~products~~ shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation ~~product~~ beyond that desired.

(b) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug preparation ~~product~~ beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug preparations ~~products~~ , cleaning, sterilization, and maintenance procedures as set forth in Board Rules.

(c) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

(d) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug preparations ~~products~~ . If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(3) Physical requirements for pharmacies compounding sterile parenteral preparations ~~products~~.

(a) A pharmacy compounding or preparing sterile parenteral preparations ~~products~~ shall have a designated area for preparing compounded, sterile parenteral preparations ~~products~~ as defined in USP 797. This area shall be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile parental preparations ~~products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.~~

(b) Equipment and supplies for compounding sterile parenteral preparations ~~products~~. A pharmacy compounding sterile parenteral preparations ~~products~~ shall have the following minimum equipment and supplies:

1. Laminar airflow hood (ISO 5) located within a ~~or class 100~~ clean room, or barrier isolator as described in USP 797;

2. Infusion pumps, if appropriate;

3. Sink, in working condition, with hot and cold running water, which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

4. Facility for light/dark field examination;

5. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents;

6. A Class II, vertical flow biological safety cabinet or appropriate barrier isolator, if chemotherapy agents are routinely prepared;

7. Refrigerator/freezer in working condition;

8. Class I or II electronic balance, or as approved in writing by the Board;

9. Disposable needles, syringes and other supplies needed for aseptic admixture;

10. Disinfectant cleaning solutions;

11. Handwashing agent with bactericidal action;

12. Disposable, lint free towels or an automatic hand dryer;

13. Appropriate filters and filtration equipment;

14. Disposable masks and sterile, disposable gloves, gowns, hair and shoe covers and goggles when indicated;

~~15. Gowns, if chemotherapy agents are routinely prepared;~~

15 ~~16.~~ An oncology drug spill kit, if chemotherapy agents are routinely prepared.

16. For the purpose of emergency or immediate patient care, compounded sterile preparations are exempted from the requirements as outlined in USP 797.

(4) Minimum equipment for pharmacies compounding non-sterile preparations ~~products~~.

(a) A compounding pharmacy must have all equipment required of a pharmacy in Chapter 480-10 of the Board Rules.

(b) Additionally, a compounding pharmacy ~~that compounds specialty products~~ must have the appropriate ~~specialty~~ equipment for use in compounding as defined in USP Chapters 795 and 797. ~~including but not limited to thermometers, pH meters, and sensitive balances appropriate for compounding these products.~~

(5) References. In addition to references required of a ~~retail~~ pharmacy, pharmacies compounding sterile pharmaceuticals shall also have a current edition of or electronic access to an established reference on IV stability and incompatibility, such as, Handbook on Injectable Drugs or King's Guide to Parenteral Admixtures, current Federal requirements for sterile compounding and other reference material including but not limited to:

(a) 'USP Pharmacists Pharmacopeia',

(6) Variances.

(a) The pharmacist-in-charge may submit to the Georgia State Board of Pharmacy a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included in the submitted request. A variance shall be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requestor will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for the variance indicated in the letter, and must be posted next to the inspection report.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86, and 26-4-110.

480-11-.05 Drug Compounding Controls.

(1) For compounding of drugs in anticipation of prescription drug orders:

(a) There shall be written procedures for the compounding of drug preparations ~~products~~ to assure that the finished preparations ~~products~~ have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure. Nothing in these rules shall prohibit or exclude the use of electronic or computer equipment to meet these requirements.

(b) Components for drug preparation ~~product~~ compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed/stored in an appropriate container), the new container shall be appropriate and shall be identified with the:

1. Component name; and

2. Weight or measure.

(c) To assure the reasonable uniformity and integrity of compounded drug preparations ~~products,~~ written procedures shall be established and followed that describe the tests or examinations to be conducted on the preparation ~~product~~ compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug preparation ~~product~~. Such control procedures shall include, but are not limited to, the following (where appropriate):

1. Capsule weight variation;

2. Adequacy of mixing to assure uniformity and homogeneity;

3. Clarity, completeness, or pH of solutions.

(d) Appropriate written procedures designed to prevent microbiological contamination of compounded drug preparations ~~products~~ purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

(e) All personnel involved in any step of the compounding process shall be clearly identified in the compounding record. The compounding record must document the following:

1. The ingredients and amounts or volumes used including the source, lot numbers and expiration dates;

2. The order of the mixing or preparation of the preparation ~~product~~ including the date mixed;

3. The identity of the pharmacist and any staff member involved in each step of the procedure; and

4. The pharmacy's lot or identification number and expiration date for the compounded drug/ preparation ~~product~~ if applicable.

(2) Compounding of drugs for an individual prescription drug order. The pharmacist must document in a readily retrievable manner, the following information:

(a) The ingredients and lot numbers used in the compounding;

(b) The amounts (weights or volumes) of each ingredient;

(c) The order of component mixing;

(d) A description of the compounding process;

(e) The name of the responsible pharmacist and all other personnel involved in each step of the compounding; and

(f) Appropriate written procedures designed to prevent microbiological contamination if the compounded prescription is purported to be sterile.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480- 11-.06 Labeling and Control of Excess Preparations ~~Products~~.

In the case where a quantity of compounded drug preparation ~~product~~ is in excess of that to be initially dispensed is prepared, the excess preparation ~~product~~ shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity as outlined in Rule 480-11-.07.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.07 Control of Components and Drug Preparation ~~Product~~ Containers and Closures.

(1) Components, drug preparation ~~product~~ containers, closures, and bagged or boxed components of drug preparation ~~product~~ containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.

(2) Drug preparation ~~product~~ containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug preparation ~~product~~ containers, and closures for use in the compounding of drug preparations ~~products~~ shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation ~~product~~ . Drug preparation ~~product~~ containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(3) Drug preparation ~~product~~ containers and closures intended for the compounding of sterile preparations ~~products~~ must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug preparation ~~product~~ containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists or under the pharmacist's supervision.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.08 Records and Reports.

(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in chapter 480-10 of the Board Rules for the retention of prescription files.

(2) All records required to be retained under this chapter or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, electronic files or other accurate reproductions of the original records. All records or reports must be producible immediately if requested by the Board or an agent of the GDNA or within forty-eight (48) hours if maintained in a central database.

(4) In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:

(a) A policy and procedure manual, including policies and procedures for cytotoxic and/or infectious waste, if applicable; and

(b) Lot numbers and expiration dates of all the components used in compounding sterile prescription drug orders.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.09 Quality Assurance Program for Compounding and Preparation of Sterile Pharmaceuticals.

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished preparations ~~products~~ shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

(a) All clean rooms, ante rooms, barrier isolators and laminar flow hoods shall be certified following procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2005) should be performed by a qualified individual no less than every six months whenever the device or room is relocated, altered, or major service to the facility is performed. ~~by an independent contractor according to Federal Standard 209E or National Sanitation Foundation Standard 49 for operational efficiency at least every twelve (12) months.~~ Appropriate documentation and records shall be maintained.

(b) There shall be written procedures developed requiring sampling if microbial contamination is suspected.

(c) If bulk compounding of parenteral solutions is performed using non-sterile chemicals, extensive end preparation ~~product~~ testing must be documented prior to the release of the preparation ~~product~~ from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.

(d) There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

480-11-.10 Exceptions.

The requirements of this chapter do no apply to the compounding or mixing of FDA-approved drugs preparations ~~products~~ pursuant to the manufacturer's directions for dispensing including but not limited to the reconstitution of oral suspensions, combination of the components of topical preparations, etc.

Authority O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-86.

- **Executive Session Items:**

Application by examination submitted by D.E.J.: Mr. Tatum made a motion to **approve** the applicant's request for examination. Mr. McPherson seconded the motion and it carried unanimously.

Application by reciprocity submitted by R.N.G.: Mr. Tatum made a motion to **deny** the applicant's request for licensure by reciprocity. However, the Board requested copy of applicant's Oklahoma disposition. Mr. Barber seconded the motion and it carried unanimously.

Application by reciprocity submitted by E.R.W.: Ms. Gardner made a motion to **approve** the applicant's request for licensure by reciprocity. Mr. Barber seconded the motion and it carried unanimously.

Application submitted by S.M.N.: Mr. Palmer made a motion to **approve** the applicant's request for Pharmacist Intern license. Mr. Tatum seconded the motion and it carried unanimously.

Application submitted by D.M.P.: Mr. Tatum made a motion to **approve** the applicant's request for Nuclear Pharmacist license. Ms. Gardner seconded the motion and it carried unanimously.

G.K.S.: Mr. Tatum made a motion to schedule an appointment for **G.K.S.** to meet with the Board at the December Board meeting. Mr. Barber seconded the motion and it carried unanimously.

Application by reciprocity submitted by Y.A.K.: Mr. Barber made a motion to **deny** the applicant's request for licensure by reciprocity. The Board further stated that applicant may reapply when other licenses are in good standing. Mr. Tatum seconded the motion and it carried unanimously.

Agenda Items:

Information submitted by Lisa M. Toliver,PHI-010686: The Board directed that a letter be mailed to the Pharmacy Intern stating that if **Ms. Toliver** is eligible for licensure, she may complete a new intern application and submit a new fee.

Information submitted by William D. Brown,RPH008463: Mr. Barber made a motion to **deny Mr. Brown's** request for an extension of continuing education hours. Try non-live C.E. courses. Mr. Tatum seconded the motion and it carried unanimously.

Information submitted by G.N.M.: Mr. Barber made a motion to **approve G.N.M.'s** request to expunge the records concerning pharmacy license suspension. Mr. Tatum seconded the motion and it carried unanimously.

Information submitted by W.K.R.: Mr. Dial made a motion to **approve W.K.R.'s** request to lift supervision of Private Consent Order. Mr. McPherson seconded the motion and it carried unanimously.

Information submitted by Jack J. Shepherd, RPH012934: The Board directed that a letter be mailed to Mr. Shepherd to meet with the Board at the January 2007 Board meeting.

Information submitted by Alan D. Edwards, RPH015329: Mr. Tatum made a motion to **approve** Mr. Edwards' request for the approved ACPE six contact hours. Mr. Palmer seconded the motion and it carried unanimously.

Information submitted by Frances Cullen Seville, P.C. for Emelia Orubele, RPH017342: Mr. Tatum made a motion to **deny** Ms. Orubele's request to lift suspension from Consent Order. She needs to retake the exam. Mr. Barber seconded the motion and it carried unanimously.

Information submitted by Ronda Cross-Scott, RPH015712: The Board directed the board staff to refer case to Drugs and Narcotics for an Investigative Interview.

Information submitted from the Legal Service Section for Michael A. Mone, Director of Regulatory Compliance: Mr. Tatum made a motion to **deny** Mr. Mone's request to release pharmacy application. Ms. Gardner seconded the motion and it carried unanimously.

Information submitted by Ken W. Schafermeyer,R.PH: The Board directed that a letter be mailed to Mr. Schafermeyer indicating that the PTCB exam is the only one it will recognize at this time.

Information submitted by Michael G. Bendinelli: Mr. Tatum made a motion to deny Mr. Bendinelli's request to enter medication orders into computer system for facilities without 24-hour pharmacy services. Mr. Barber seconded the motion and it carried unanimously.

Rule 480-15 – Penalties: The Board table until the next Board meeting December 6, 2006.

Information submitted by Gregory W. Walter, MD,FACEP: The Board directed that a letter be mailed to Dr. Walter indicating that the Board has no authority in this matter. The Board suggested that Dr. Walter contact the Composite State Medical Board or the Center for Disease Control.

Newly Licensed Pharmacists dated 10/01/06-11/01/06: Mr. Palmer made a motion to **approve** the newly licensed Pharmacists with the exception of J.K.C. Ms. Gardner seconded the motion and it carried unanimously.

License Number	Name	Profession	Issue Date
RPH023377	Patel, Jayna Girish	Pharmacist	10/2/2006 00:00:00
RPH023378	Woodruff, Quin	Pharmacist	10/2/2006 00:00:00
RPH023379	Hyatt, Jacqueline Christine	Pharmacist	10/2/2006 00:00:00
RPH023380	Pittman, David Michael	Pharmacist	10/2/2006

			00:00:00
RPH023381	Hitzeman, Andrea Littlejohn	Pharmacist	10/2/2006 00:00:00
RPH023382	Wilson, Matthew Robert	Pharmacist	10/4/2006 00:00:00
RPH023383	Martin, Sharon Lorena	Pharmacist	10/4/2006 00:00:00
RPH023384	Dumas, Katherine Marie	Pharmacist	10/4/2006 00:00:00
RPH023385	Brown, Tonya White	Pharmacist	10/4/2006 00:00:00
RPH023386	Berkeley, Karen Lynette	Pharmacist	10/4/2006 00:00:00
RPH023387	Oyenuga, Linda Adedoyin	Pharmacist	10/5/2006 00:00:00
RPH023388	Ellis, Ginger Renae	Pharmacist	10/5/2006 00:00:00
RPH023389	Delaune, Betsy Briones	Pharmacist	10/5/2006 00:00:00
RPH023390	Allen, Judith Alia	Pharmacist	10/5/2006 00:00:00
RPH023391	Lutta, Davies Branson	Pharmacist	10/10/2006 00:00:00
RPH023392	Offor, Gregory Chinedu	Pharmacist	10/12/2006 00:00:00
RPH023393	Bell, Amber Vivian	Pharmacist	10/13/2006 00:00:00
RPH023394	Word, Michelle Shepler	Pharmacist	10/13/2006 00:00:00
RPH023395	Oraekwe, Peter Chukwudiebele	Pharmacist	10/13/2006 00:00:00
RPH023396	Honeycutt, Hayden Parker	Pharmacist	10/13/2006 00:00:00
RPH023397	Thomas, Alison Lyons	Pharmacist	10/17/2006 00:00:00
RPH023398	Nettles, Columbus R.	Pharmacist	10/17/2006 00:00:00
RPH023399	Jafarian, Minoo	Pharmacist	10/17/2006 00:00:00
RPH023400	Pham, Aidiem Dinh	Pharmacist	10/17/2006 00:00:00
RPH023401	Mowatt, Carolyn Ann Marie	Pharmacist	10/18/2006 00:00:00
RPH023402	Wilson, Cassie Ann	Pharmacist	10/19/2006 00:00:00
RPH023403	Hawkins, Amber Shanee	Pharmacist	10/23/2006 00:00:00
RPH023404	Phillips, Joseph Leonard	Pharmacist	10/23/2006 00:00:00
RPH023405	Kennedy, Christine Joy	Pharmacist	10/24/2006 00:00:00
RPH023406	Rab, Saira	Pharmacist	10/24/2006 00:00:00
RPH023407	Nguyen, Huong Thi	Pharmacist	10/24/2006 00:00:00
RPH023408	Walker, Quatata Latell	Pharmacist	10/26/2006 00:00:00
RPH023409	Doe, George Akin	Pharmacist	10/26/2006 00:00:00
RPH023410	Daniel, Elizabeth Lukose	Pharmacist	10/27/2006

			00:00:00
RPH023411	Chak, Andrea Jeannine	Pharmacist	10/27/2006 00:00:00
RPH023412	Bonner, LaToya Ann	Pharmacist	10/30/2006 00:00:00
RPH023413	Nguyen, My-Linh	Pharmacist	10/30/2006 00:00:00
RPH023414	Jackson, Deidre Chante	Pharmacist	10/31/2006 00:00:00
RPH023415	Kowalewski, Edward W.	Pharmacist	10/31/2006 00:00:00

Newly Licensed Pharmacist Interns dated 10/01/06-11/01/06: Mr. Palmer made a motion to **approve** the newly licensed Pharmacist Interns. Ms. Gardner seconded the motion and it carried unanimously.

License Number	Name	Profession Type	Issue Date
PHI-013049	Weinstein, Michael Seth	Pharmacist Intern	10/2/2006 00:00:00
PHI-013050	El Kour, Mirna Yousef	Pharmacist Intern	10/3/2006 00:00:00
PHI-013051	Ali-Sairany, Helen A.	Pharmacist Intern	10/4/2006 00:00:00
PHI-013052	Luschen, Robert Cecil	Pharmacist Intern	10/4/2006 00:00:00
PHI-013053	Pitts, Liza Kay	Pharmacist Intern	10/4/2006 00:00:00
PHI-013054	Campaign, Jessica Elaine	Pharmacist Intern	10/12/2006 00:00:00
PHI-013055	Tucker, Rebekah Eileen	Pharmacist Intern	10/12/2006 00:00:00
PHI-013056	Price, Bobby Jermaine	Pharmacist Intern	10/16/2006 00:00:00
PHI-013057	Boateng, Akosua Kumiwa	Pharmacist Intern	10/19/2006 00:00:00
PHI-013058	Griffin, Demetria Michelle	Pharmacist Intern	10/23/2006 00:00:00
PHI-013059	Olaniyi, Ajibola Akinyemi	Pharmacist Intern	10/23/2006 00:00:00
PHI-013060	Bryant, Brittany Lynn	Pharmacist Intern	10/24/2006 00:00:00
PHI-013061	Gillette, Katherine Park	Pharmacist Intern	10/24/2006 00:00:00
PHI-013062	Renukuntla, Bharaneeshwar	Pharmacist Intern	10/24/2006 00:00:00
PHI-013063	Badr, Mathur Husam	Pharmacist Intern	10/26/2006 00:00:00

Draft of September 13, 2006 Board meeting minutes: Mr. McPherson made a motion to **approve** the Board Minutes with corrections. Mr. Barber seconded the motion and it carried unanimously.

Draft of October 11, 2006 Board meeting minutes: Mr. McPherson made a motion to **approve** the Board Minutes with correction of Executive Session Item One, J.K.C. Ms. Gardner seconded the motion and it carried unanimously.

OTHER BUSINESS:

Information submitted by Othniel T. Smith,RPH0173003: Mr. Tatum made a motion to send a letter to Mr. Smith to request an appearance with the Board and bring advocate. Mr. Barber seconded the motion and it carried unanimously.

Information submitted by Nicholas M. Billirakis,RPH009721: Mr. Palmer made a motion **deny** Mr. Billirakis's request. The Board recommends Mr. Billirakis to reschedule the continuing education course

with the University of Georgia or wherever a course is available. Mr. Tatum seconded the motion and it carried unanimously.

Information submitted by Monifa Young-Mwangi,RPH021894: Mr. Tatum made a motion to **approve** Ms. Mwangi's request for appointment with the Board at the next available meeting to discuss possible reinstatement of pharmacist license. Mr. Barber seconded the motion and it carried unanimously.

Information submitted by Frances Cullen Sevillle,P.C. for James Wilson,RPH010787: Mr. Tatum made a motion to **deny** request. The Board recommends Mr. Wilson to reapply after South Carolina sanctions have been completed. Mr. Palmer seconded the motion and it carried unanimously.

Information submitted by A. Leroy Toliver for J. Keith Herrington,RPH019375: Mr. Tatum made a motion to **approve** request to lift supervision restriction in Consent Order. Mr. Barber seconded the motion and it carried unanimously.

Information submitted by A.W.: Mr. Barber made a motion to **approve** A.W.'s request to receive five Veteran points to examination score. Ms. Gardner seconded the motion and it carried unanimously.

Information submitted by A. Leroy Toliver for Kurt Boesger,RPH015299: Mr. Palmer made a motion to **approve** Mr. Boesger's request to lift supervision in Consent Order. Mr. Dial seconded the motion and it carried unanimously.

Information submitted by T.W.B.: Mr. Palmer made a motion to **deny** T.W.B.'s application for licensure. Mr. Tatum seconded the motion and it carried unanimously.

Information submitted by E.R.W.: Mr. Barber made a motion to **approve** E.R.W.'s application for licensure. Mr. Tatum seconded the motion and it carried unanimously.

There being no further business, the meeting adjourned at 3:20 p.m.

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Bill Prather, President

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Lisa Durden, Executive Director
Professional Licensing Boards Division

Minutes Prepared By: Dianne W. Patterson, Administrative Assistant
Reviewed/Edited By: Lisa Durden Executive Director

Minutes approved by the Board at its December 6, 2006 Board meeting.